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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,618	11/05/2003	MacDonald S. Morris	56297-5011-02	4873

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EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/700,618

Applicant(s)

MORRIS ET AL.

Examiner

Frank W. Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003 and 18 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 58-74 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>11/03, 11/04, and 4/05</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

PRELIMINARY AMENDMENTS

1. PRELIMINARY AMENDMENTS filed on November 5, 2003 and April 18, 2005 have been entered.

Specification

2. The amendment filed on November 5, 2003 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material "This is a divisional of U.S. application no. 10/226,355, filed August 23, 2002 which is a divisional of U.S. application no. 08/626,285, filed April 4, 1996, now U.S. Pat. No. 6,458,530; all of which are herein incorporated by reference" is not supported by the original disclosure because the original disclosure does not indicate to incorporate U.S. application No. 10/226,355 and U.S. application No. 08/626,285 by reference.

Applicant is required to cancel the new matter in the reply to this Office Action.

3. The disclosure is objected to because of the following informalities: (1) there are several nucleotide sequences having more than 10 nucleotides in Figure 3. However, there are no SEQ ID Nos in either Figure 3 or BRIEF DESCRIPTION OF THE DRAWING of the specification related to Figure 3; and (2) there are several nucleotide sequences having more than 10 nucleotides in pages 37, 39, 54, and 55 of the specification. However, there are no SEQ ID Nos for these nucleotide sequences in pages 37, 39, 54, and 55 of the specification.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. New Matter

Claims 58-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although the specification describes that “the tag nucleic acid is selected from a group of tag nucleic acids which do not cross-hybridize and which have a substantially similar T_m” (see page 5, lines 31 and 32), since tag nucleic acids are different from the probes recited in claim 58, page 5, line 31 of the specification suggested by applicant fails to define or provide any disclosure to support the phrase “the probes are selected to have a substantially similar melting temperature;” as recited in (b) of claim 58 and 74. Although the specification describes that “the set of tag nucleic acids comprises from 100-100,000 tags. Typically, a tag set will include between about 500 and 15,000 tags. Usually, the number of tags in a tag set is between about 5,000 and about 14,000 tags. In one preferred embodiment, a set of tags of the invention comprises about 8,000-9,000 tags” (see page 5, lines 16-19), since tag nucleic acids are different from the probes recited in claim 58, page 5, lines 16-18 of the specification suggested by

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applicant fails to define or provide any disclosure to support the phrase “the array contains probe sets complementary to at least 100 tag nucleic acids” as recited in (f) of claims 58 and 74 and claims 68-71. Although the specification describes that Tms of 20mer tag sequences are within plus or minus 7°C (see page 35, 7-9 and Table 1), since tag nucleic acids are different from the probes recited in claim 58, page 35, line 16 and Table 1 of the specification suggested by applicant fail to define or provide any disclosure to support claim 59. Although the specification describes that “the tags differ by about 5 nucleotides when aligned for maximal correspondence (e.g., where the tags are 20-mers)” (see page 20, line 15-24), since tag nucleic acids are different from the probes recited in claim 58, page 20, lines 22-24 of the specification suggested by applicant fails to define or provide any disclosure to support claim 62. Although the specification describes that “[T]he size of the tags can vary substantially, but is typically, from about 8-150 nucleotides, more typically between 10 and 100 nucleotides, often between about 15 and 30 nucleotides, generally between about 15 and 25 nucleotides and, in one preferred embodiment, about 20 nucleotides in length” (see page 3, lines 29-32), since tag nucleic acids are different from the probes recited in claim 58, page 3, lines 30-32 of the specification suggested by applicant fails to define or provide any disclosure to support claims 64-66.

MPEP 2163.06 notes “If NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. *IN RE RASMUSSEN*, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981).” MPEP 2163.02 teaches that “Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application”.

Conclusion

6. No claim is allowed.
7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

October 1, 2006



**FRANK LU
PRIMARY EXAMINER**